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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/930,821	08/15/2001	Atsuo F. Fukunaga		2396

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EXAMINER	
WEISS JR, JOSEPH FRANCIS	
ART UNIT	**PAPER NUMBER**
3743	17

DATE MAILED: 12/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/930,821	FUKUNAGA ET AL.	
	Examiner	Art Unit	
	Joseph F Weiss Jr.	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 13-22 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 13-22 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Claim Rejections - 35 USC § 102

I. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

II. Claims 13-14 & 17-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Palleni (US 3964476).

In regards to claim 13, Palleni discloses a multi lumen proximal connector, (26), for a multilumen unilimb breathing circuit for connecting at least two flexible tubes to a multi-lumen proximal terminal comprising a multilumen proximal terminal (Sub-housing that surrounds/defines 56) comprising a multilumen proximal fitting (sockets 58 of Fig 4 & corresponding portion of 42), proximal terminal a rigid housing (50 fig 5) having two independent lumens (42 & 56) having a proximal machine end (that portion of the housing that has various interconnecting hoses between the ventilator's proximal terminals and the housing 50 of 26) and a distal patient/unilimb hose end (point of interface with unilimb 24) wherein said fitting "can be" directly attached to a mating, rigid multi-lumen proximal terminal, this terminal having first and second ports at its distal end of third and forth lumens so that when the proximal ends of the first and second lumens of the of the fitting are operatively attach to the first and second ports they establish a flow path with the corresponding third and forth lumens of the proximal terminal such that the flow paths defined by the lumens are independent wherein the fitting is fully capable of being operatively attachable to and detachable from a mating, "rigid" proximal terminal by a user at the site of use and which "can" be used to "operatively" connect a "flexible" multilumen patient respiratory conduit to a proximal terminal of an assisted ventilation or anesthesia machine.

In regards to claim 14, Palleni discloses the lumens as being co-axial.

In regards to claim 17, Palleni discloses the lumens terminating in third and fourth distal ports and fifth and sixth proximal ports wherein the ports are co-axial.

In regards to claim 18, Palleni discloses a unilimb respiratory conduit (24) for artificial respiration, for use with a proximal terminal, such a terminal having lumens for ingress and egress of respiratory gasses in independent flow paths which are operatively independently connectable, the unilimb conduit comprising "flexible" tubing forming a first and second lumens forming independent flow paths having a distal patient end and a proximal machine end, the distal end being operatively connectable/detachable to a patient by a user at the site of use (note interface 28A & 13B) and said proximal end is of said conduit is operatively connectable/detachable from a proximal terminal by a user at the site of use (note the above rejection of claim 13), wherein when they are connected at the proximal terminal the first lumen is in fluid communication with inspiratory flow path and second lumen in fluid communication with the expiratory flow wherein the first lumen is operatively connectable to the inspiratory gas via the proximal terminal, while the second lumen is operatively connectable to the expiratory outlet via a proximal terminal wherein the respiratory conduit is fully capable of operatively attachable to and detachable from a proximal terminal after use for independent disposal or sterilization by a user at the site of use.

In regards to claim 19, Palleni discloses a respiratory conduit interface device (26) capable of operative coupling to the unilimb, multi lumen, flexible respiratory conduit of the type described in claim 18, as noted in the above rejection to claim 18 which is herein incorporated by reference, to a respiratory device comprising a rigid housing (58) with first and second lumens defining first and second independent flow paths and having a proximal (machine) end and a distal (patient) end and wherein said flow paths diverge from each other proximally of said distal end of said housing so that the proximal end of said first lumen is independently connectable to an inlet for a source of inspiratory gas (connectivity of 32) while the proximal end of the second

lumen is independently operatively connectable to an expiratory outlet, wherein the hose of claim 18 is operatively attachable to the housing for use and detachable for disposal/sterilization.

In regards to claim 21, Palleni discloses the multi-lumen proximal fitting of claim 13 further comprising an interface device (28) wherein said fitting "can" be "operatively" attached to and detached from said interface device by a user at a site of use, said interface device comprising a rigid housing (62) having third and forth lumens (78 & the interior of 70) independent of each other and each having a proximal and distal end (note the device has a length and opposing ends which the lumens run the length thereof and that the device is end to end oriented relative to a user and thus has proximal & distal ends) and which converge at a distal end (note 72/76) and which is capable of simultaneous "operative" connection to a unilimb flexible respiratory conduit (note 62 & 64) and has third and fourth flow paths ion said housing diverge from each other proximally of said distal end of said housing to so that said proximal end of said third lumen is independently operatively connectable to an inlet for a source of inspiratory gas (32/64) while said proximal end of said fourth lumen is independently operatively connectable to an expiratory outlet (62) wherein a unilimb flexible respiratory conduit (24) is operatively attachable to said housing for use and detachable therefrom after use for independent disposal or sterilization via said proximal fitting.

In regards to claim 22, Palleni discloses the proximal connector further comprising a multi-lumen patient respiratory conduit (24) connected to said fitting, wherein a fith & sixth lumen are within said flexible respiratory conduit (see fig 3) and at least a portion of the fifth lumen continues said first flow path and at least a portion of said six lumen continues said second flow path, wherein said first flow path and said second flow path are independent for at least a portion of the length of said flexible respiratory conduit.

Claim Rejections - 35 USC § 103

III. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be

patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

IV. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Palleni.

In regards to claim 20, the reference noted above substantially disclose the claimed invention to include the respiratory conduit being operatively attachable and detachable (see any fig) but does not disclose the interface being "permanently" connected to a machine. It is noted that applicant's specification does not set forth this "permanent" attachment, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art. Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary. Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather that to constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary. (See Fukunaga 4265235)

V. Claims 15& 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palleni in view of Lorenzen (US 5715815).

In regards to both claims 15 & 16 Palleni substantially discloses the instant application's claimed invention, but does not explicitly disclose the use of a filter in a lumen of the connector. However, Lorenzen disclose such (element 50). The references are analogous since they are from the same field of endeavor, the respiratory arts and the same problem solving area, the interconnection of multi-lumen apparatuses to a respiratory device. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Lorenzen and used them with the device of Palleni. The suggestion/motivation for doing so would have been to reduce the likelihood of pulmonary

infection in a patient/user. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather that to constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

Response to Arguments

1. Applicant's arguments filed 9 Oct 03 have been fully considered but they are not persuasive.

Applicant's usage of "multi-lumen proximal fitting" or "proximal terminal" are note provided with unique definitions in applicant's written description, and there is no terminology used that one of ordinary skill in the art would give art specific meaning. Thus any co-axial fitting that meets all of the structural limitations meets the language as set forth by applicant. Thus the sue of these terms are a mere label for what is actually being structurally presented, a co-axial fitting and amount to a difference without a distinction in the final analysis as noted in the above rejection.

The manner of the provision and removal of gases is irrelevant to the positively claimed structure and cannot serve as a structural distinction, applicant is not claiming a system and its arrangement, but is only positively claiming the specifically noted sub-components.

Detachability is also structurally irrelevant. However, to address applicant's concern over this non-structural feature please note that Palleni uses the term "socket" to describe the interface between the hoses and his co-axial fittings. Sockets are inherently releaseably engaging for whatever they are designed to interface with, e.g. corrugated tubing, electrical plugs etc. The

term "secured" that applicant hangs his hat on to prove lack of detachability is not persuasive because something can be secured and still be releaseable. I.e. the term and its usage by Palleni does not mean permenantly secured, but instead is silent on the form of securement. But when read in the context and entirety of the reference (e.g. in light of the use of the term socket) one of ordinary skill in the art would have a reasonable basis to conclude that the securement is relaseable. Thus applicant's argument is not persuasive.

The time period and teachings of other references are irrelevant to the teaching of the Palleni, Palleni is the evidence of record not applicant's or any other inventor's contemporaneous disclosures. Please point to a teaching in Palleni in order to patently distinguish over the prior art and/or provide additional limitations to applicant's claimed invention to patently distinguish over the prior art.

Conclusion

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F Weiss Jr. whose telephone number is 703-305-0323. The examiner can normally be reached on M-F, 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 703-308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Jfweiss
12/17/03

Aaron J. Lewis
Primary Examiner